IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kai Donsbach et al.	Examiner: Dr. Laura Stockton
Serial No.: 11/462,531	Group Art Unit: 1626
Filed: August 4, 2006	Confirmation No.: 5299

For: CRYSTALLINE FORM OF TELMISARTAN SODIUM

BRIEF ON APPEAL UNDER 37 C.F.R. § 41.37

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal from the decision of the Examiner finally rejecting claims 1-6 of the above-identified application.

(1) REAL PARTY IN INTEREST

The application is assigned of record to Boehringer Ingelheim Pharma KG, who is the real party in interest herein.

(2) RELATED APPEALS AND INTERFERENCES

Appellants, their legal representative and the assignee are not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

(3) STATUS OF THE CLAIMS

Claims rejected: Claims 1-6.

Claims allowed: (none)

Claims canceled: (none)

Claims withdrawn: (none)

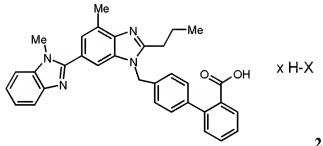
Claims on Appeal: Claims 1-6 (Copy of claims on appeal in attached Appendix).

(4) STATUS OF AMENDMENTS

An Amendment after the Final Rejection was filed on November 10, 2008, and was indicated by the Examiner to be entered for purposes of the appeal; see the Advisory Action mailed January 5, 2009. The entered amendments made only non-substantive changes to the claims.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention (independent claim 1) is directed to compounds of formula **2**



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wherein H-X denotes an acid selected from the group consisting of toluenesulphonic acid and methanesulphonic acid; see, e.g., page 9, lines 4-11, of the instant specification. Claims 3, 4 and 6 are directed to these acid addition salts in crystalline form; see, e.g., page 13, lines 7-8, of the instant specification. (Appellants note that claim 6 mistakenly depends on claim 3 instead of claim 4 and a corrective amendment will be filed should the rejection be reversed.)

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following outstanding grounds of rejection are requested to be reviewed on appeal. For each ground, any separate consideration of the claims subject to that rejection are indicated.

1. The rejection of claims 1-6, on appeal, under 35 U.S.C. §103 as being obvious to one of ordinary skill in the art over DeGasparo (WO 97/31634) and Hauel (U.S. Patent No. 5,594,003), each taken alone or in combination with each other.

a. Claims 1, 2 and 5, on appeal, are grouped together.

b. Claims 3, 4 and 6, on appeal, are separately grouped together for the reasons given in the argument.

(7) ARGUMENT

1a. Claims 1, 2 and 5, on appeal, are not obvious to one of ordinary skill in the art under 35 U.S.C. §103 over DeGasparo (WO 97/31634) and Hauel (U.S. Patent No. 5,594,003), each taken alone or in combination with each other, thus, the rejection should be reversed.

DeGasparo teaches the use of angiotensin receptor antagonists for stimulating apoptosis and, thus, for use in treating hypertension; see, e.g. page 1. DeGasparo refers to several EP and WO publications for providing compounds for use in its methods; see, e.g., pages 2-8. However, DeGasparo itself only specifically or generically describes 11 compounds for use in its methods, i.e., the 11 structures shown at pages 2-8 and elsewhere in the reference. DeGasparo also provides a generic description at page 8, first full paragraph, that certain of these compounds which possess at least one basic centre can form acid addition salts. A large listing of the acids which can potentially form acid addition salts is

provided. Included in that large listing are methanesulfonic acid and p-toluenesulfonic acid, among many others.

DeGasparo does not disclose the base compound shown by formula 2 of claim 1, on appeal, let alone the toluenesulphonic acid or methanesulphonic acid addition salt thereof. DeGasparo discloses a compound of the structure shown at the top of page 5 which is purported to be "Telmisartan" but this compound is not of the structure shown for appellants' formula 2 and not of the structure generally accepted for Telmisartan. The compound shown by this structure in DeGasparo has an n-butyl group (i.e., 4 carbon atom group) on the left hand side of the structure shown, i.e., at the 2-position of that benzimidazole group. The base compound of appellants' formula **2** has an n-propyl (i.e., 3 carbon atom group) at the corresponding position. Thus, the instant claims on appeal are distinct from DeGasparo at least in this respect. The Final – and preceding – Office actions fail to provide any articulated reasoning for why one of ordinary skill in the art would modify the compound of DeGasparo in the manner necessary to arrive at the claimed base structure; see, e.g., KSR International Co. v. Teleflex Inc., 550 U.S. _, 82 USPQ2d 1385, at 1396 (2007), stating: "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

Additionally, despite the generic recitation at page 8 of DeGasparo, appellants urge that the reference fails to fairly suggest the specific toluenesulphonic acid or methanesulphonic acid addition salts of the instant claims. Although for the reasons stated above, DeGasparo does not even generically encompass the claimed invention, even if it did, it is not the law that "regardless of how broad, a disclosure of a chemical genus renders obvious any species which happens to fall within it," see, e.g,. In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992); and, In re Baird, 29 USPQ2d 1550 (Fed. Cir. 1994). Instead, the disclosure

must be considered as a whole as to whether it fairly suggests the claimed invention to one of ordinary skill in the art. DeGasparo discloses several compounds, none of which are of appellants' base structure and only one of which is of similar structure. It also discloses that, when a basic centre is present, any of a large number of acid addition salts can be formed. There are no examples of any specific salts of these compounds and no direction to pick any specific one of these salts. Further, there is no indication that the compound shown on page 5 is one of the compounds which can form the acid addition salts. Appellants urge that there is no fair suggestion from DeGasparo to select the one compound shown at the top of page 5 from among the others, modify that compound to arrive at the base structure of formula **2** and then choose to provide that modified compound as an acid addition salt of toluenesulphonic acid or methanesulphonic acid from among the many other possible salts generically described by DeGasparo. In the absence of any direction to combine these several selections and modifications, there is no fair suggestion of the claimed invention from DeGasparo.

For all of the above reasons, it is urged that the rejection under 35 U.S.C. §103 based on DeGasparo alone should be reversed.

Hauel discloses compounds of the general formula (I) (col. 1) and also teaches their use as angiotensin antagonists. From the definition of the options for the variables in Hauel's formula (see col. 1, line 50, to col. 7, line 27) it should be clear that Hauel's formula encompasses an extremely large scope of compounds. Hauel also recites a very large number of specific compounds in its 233 Examples from cols. 57-125, many of which recite more than one specific compound. Among all of these compounds, Hauel recites the compound 4'-[[2-n-propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)-benzimidazol-1-yl]-methyl]-biphenyl-2-carboxylic acid. Hauel also provides at col. 52, lines 31-34, a very brief and non-specific statement that the "physiologically acceptable salts" of the compounds of general formula I

also possess the angiotensin antagonist properties. Further, at col. 51, lines 1-7, it recites that the compounds can be converted into acid addition salts and mentions 10 specific acids for such conversion. No specific salt form compounds are described and none of the examples are of salt forms of the compounds.

The 4'-[[2-n-propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)-benzimidazol-1-yl]-methyl]-biphenyl-2-carboxylic acid compound recited in Example 9 of Hauel is of the structure of the base compound of formula **2** in the claims on appeal. But Hauel provides no description or suggestion of a toluenesulphonic acid or methanesulphonic acid addition salt of this compound. The Final Office action mailed June 13, 2008, (page 3), states incorrectly that Hauel teaches the hydrochloric, hydrobromic, toluenesulphonic acid or methanesulphonic acid addition salt of this compound. In fact, at col. 51, lines 1-7, Hauel does generically mention hydrochloric and hydrobromic acids as suitable acids for making addition salts. But Hauel makes no mention of toluenesulphonic acid or methanesulphonic acid addition salts of this or any other compound. Hauel does mention p-toluenesulphonic acid and methanesulphonic acid at col. 36, lines 59-60, and this was relied on in previous Office actions. However, this disclosure has no relation to making salt forms of the compounds. The acids are disclosed here as condensing agents in an intermediate step of making the compounds. Hauel provides no suggestion to provide toluenesulphonic acid or methanesulphonic acid addition salts of any compound including the compound of formula **2** of the instant claims on appeal.

Accordingly, despite the broad recitation in Hauel that acid addition salts can be used, appellants urge that the reference fails to fairly suggest the specific toluenesulphonic acid or methanesulphonic acid addition salts of the instant claims. Such a broad disclosure does not support obviousness of a specific acid addition salt of a specific compound; see, e.g,. In re

Jones and In re Baird, cited above. The Hauel disclosure as a whole fails to fairly suggest the claimed invention to one of ordinary skill in the art. Hauel discloses an extremely large number of compounds encompassed by its formula (I) and recited in its many examples. It also provides only a broad generic recitation to provide acid addition salts and the specific ones it suggests at col. 51, lines 1-7, do not include toluenesulphonic acid or methanesulphonic acid addition salts. There are no examples of any specific salts of any compound, let alone appellants' specific compound, and no direction to pick toluenesulphonic acid or methanesulphonic acid for forming a salt of this compound. In the absence of any such direction towards the very specific salts of the claims on appeal, there is no fair suggestion of the claimed invention from Hauel.

For all of the above reasons, it is urged that the rejection under 35 U.S.C. §103 based on Hauel alone should be reversed.

Regarding the combination of DeGasparo and Hauel, it is noted that the Final Office action provides no articulated reasoning of why one of ordinary skill in the art would combine the teachings of these references and what aspects of the references one of ordinary skill in the art would have reason to combine in a manner which suggests the claimed invention. Thus, there is no articulated reason provided to support the rejection based on the combination of the references. In any event, the arguments made above as to references individually are equally applicable for establishing the nonobviousness of the claimed invention over the combined reference teachings. Whether separate or combined, the references fail to provide teachings which would give one of ordinary skill in the art reason to provide one of the two very specific acid addition salts of the very specific base compound of appellants formula **2**.

For all of the above reasons, it is urged that the rejection under 35 U.S.C. §103 based

on the combination of DeGasparo and Hauel should also be reversed.

1b. Claims 3, 4 and 6, on appeal, are not obvious to one of ordinary skill in the art under 35 U.S.C. §103 over DeGasparo (WO 97/31634) and Hauel (U.S. Patent No. 5,594,003), each taken alone or in combination with each other, thus, the rejection should be reversed.

All of the arguments from Issue 1a. above apply equally in traversing the rejection on the same grounds of claims 3, 4 and 6, on appeal, and are incorporated herein by reference. For those reasons at least, the rejection of these claims should also be reversed. But additional basis is provided for reversal of the rejection of these claims.

Claims 3, 4 and 6, on appeal, are directed to the specifically claims salts provided "in crystalline form." As pointed out above, neither of DeGasparo or Hauel disclose the specific salts as claimed – or any salts. The references certainly do not disclose these salts in crystalline form. Further, neither of the references provide even a mention, specifically or generally, of providing crystalline forms of the salts of the compound or that such forms are possible. The Final Office action provides no mention at all of crystalline forms or why the claims on appeal directed to these forms would be obvious. No basis for their rejection is apparent on the record.

For this additional reason, it is urged that the rejection of claims 3, 4 and 6, on appeal, under 35 U.S.C. §103, as being obvious over DeGasparo or Hauel, or their combination, should be reversed.

For all of the above reasons, it is urged that the decision of the Examiner rejecting claims 1-6, on appeal, is in error and should be reversed.

Reversal of the rejection is therefore mandated by law, and is respectfully and courteously requested.

Respectfully submitted,

/John A. Sopp/

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Under 37 C.F.R. §1.34

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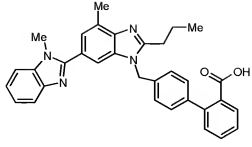
(VIII) CLAIMS APPENDIX

1. A compound of formula **2**



x H-X

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wherein H-X denotes an acid selected from the group consisting of toluenesulphonic acid and methanesulphonic acid.

2. The compound of formula **2** according to claim 1, wherein H-X denotes toluenesulphonic acid.

3. The compound of formula **2** according to claim 1, in crystalline form.

4. The compound of formula **2** according to claim 1, wherein H-X denotes methanesulphonic acid.

5. The compound of formula **2** according to claim 2, in crystalline form.

6. The compound of formula **2** according to claim 3, in crystalline form.

(IX) EVIDENCE APPENDIX

[None]

(X) RELATED PROCEEDINGS APPENDIX

[None]